

REMARKS

In the Office Action, claims 11-15, 22 and 23 were rejected under 35 U.S.C. § 102 (b) as being anticipated by WO 97/12637<sup>1</sup>. Claims 16 and 21 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over WO 97/12637. Claims 17-20 were objected to as being dependent on a rejected base claim.

In this response, claim 11 has been amended. Upon entry of the amendments, claims 11-23 will be pending.

Reconsideration of the application is respectfully requested based on the following remarks.

Rejection under 35 U.S.C. § 102 (b)

Claims 11-15, 22 and 23 were rejected under 35 U.S.C. § 102 (b) as being anticipated by WO 97/12637.

WO 97/12637 describes a system for determining the efficacy of sterilization cycles in sterilizers. In an embodiment, device 1 to be located in a sterilization chamber includes a tube 2 and a bore 3, a single conically shaped stage, with a sensor 7 disposed at the closed end of the tube. *See Fig. 3.* In another embodiment, the bore is divided into several equally-sized communicating compartments 47, wherein one compartment 47 at one end of bore 3 incorporates opening 5, and another compartment 47 at the other end of bore 3 incorporates sensor 7. *See Fig. 6.*

Though WO 97/12637 discloses a single conical stage, the Examiner asserts that WO 97/12637 nevertheless anticipates independent claim 11 because the cone could be divided into multiple imaginary sections or stages. Applicant respectfully disagree that the claims can be reasonably interpreted to include a gas collection volume having a single shape.

However, in order to remove any doubt, Applicant has amended independent claim 11 to specify the multiple stages are arranged longitudinally and that a cross-sectional area of each stage is constant over a predetermined longitudinal distance. Support for the amendment is found, for example, at Figure 1 of the originally filed specification.

Applicant respectfully submits that WO 97/12637 does not describe a gas collection volume having multiple stages arranged longitudinally, wherein a cross-sectional area of each

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<sup>1</sup> In the Office Action on page 2, section 1, the Examiner indicates that claim 20 is rejected, but the Examiner does not indicate the grounds for rejection. On pages 1 and 4, claim 20 is indicated as objected to. Applicant thus assumes that claim 20 is objected to and not rejected.

stage is constant over a predetermined longitudinal distance. On the contrary, WO 97/12637 describes a device including a single conical stage in Fig. 3. Even if the conical shape were divided into imaginary sections, none of those sections would have a constant cross-sectional area over a predetermined longitudinal distance.

Applicant further submits that the claimed invention operates on a very different functional principle from the device of WO 97/12637, which includes a heat sink portion that receives heat from a free space, tube 2 with bore 3. See p. 5, line 24 to p. 6, lines 16-18. During a sterilization process, condensate forms within the bore and drains away, with non-condensable gas remaining in the bore and hindering entry of a sterilant. See p. 8, lines 29 to p. 9, line 6. Accordingly, the tube should be made of materials having appropriate thermal properties so as to detect an effective sterilization. See p. 9, lines 6-8. By contrast, the test device according to the present invention is based on a concentration of air or remaining gases directed towards the detector volume. The stage closest to the detector simulates inaccessible surfaces. The implementation of multiple distinct stages each having a decreasing cross sectional area and volume leads to an amplifying effect as a result of a concentration of the remaining air or other non-condensable gases in the stage neighboring the detector volume. Thus, the testing device according to the present invention defines specific geometric parameters and, unlike the device of WO 97/12637, is not reliant on thermal properties of the components. Therefore, in addition to not disclosing all of the features of claim 1, the device of WO 97/12637 is based on different functional principles.

Because WO 97/12637 does not describe each and every feature of independent claim 11, and because claims 12-15, 22 and 23 depend from claim 11, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

Rejections under 35 U.S.C. § 103 (a)

Claims 16 and 21 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over WO 97/12637.

As set forth above, WO 97/12637 does not describe the feature of independent claim 11 a gas collection volume having multiple stages, wherein a cross-sectional area of each stage is constant over a predetermined longitudinal distance. Because claims 16 and 21 depend from claim 11 and therefore include the features of claim 11, withdrawal of the rejection under 35 U.S.C. § 103 (a) is respectfully requested.


CONCLUSION

Applicant thanks the Examiner for deeming claims 17-20 allowable if written in independent form. In view of the foregoing amendment and arguments, Applicant believes the application is in condition for allowance.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

The Commissioner is hereby authorized to charge any unpaid fees deemed required in connection with this submission, including any additional filing or application processing fees required under 37 C.F.R. §1.16 or 1.17, or to credit any overpayment, to Deposit Account No. 12-1216.

Respectfully submitted,



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Date: August 10, 2010